

REMARKS

Claims 1 – 5, 7 – 14, and 16 are currently pending. Claims 1 and 2 are the pending independent claims. In the Office Action, Claim 13 was objected to as allegedly being in improper multiple dependent form. Claim 15 was rejected under Section 112, second paragraph as allegedly being indefinite and under Section 101 as allegedly being an improper process claim. On the merits, Claims 1 – 12 and 14 were rejected under Section 102 as allegedly being anticipated by U.S. Patent No. 6,602,522 to Chen et al. (“Chen”). Finally, Claims 13 and 15 were rejected under Section 103 as allegedly be obvious over Chen in view of U.S. Patent No. 7,018, 658 to Platteeuw.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. Objection to Claim 13.

The Examiner first objects that Claim 13 is of improper form because “a multiple dependent claim should recite in the alternative.” The basis for this objection is not understood because the language of the claim was drafted in an alternative form referring to “any of the preceding claims” which is expressly approved of in the M.P.E.P. at Section 608.01 (n) in the subsection entitled “Acceptable Multiple Dependent Claim Wording.” The issue is now moot, however, as the Applicants have decided to remove the multiple dependency and make Claim 13 to depend from Claim 1 alone.

II. Section 101 and 112 Rejections of Claim 15.

The Examiner also rejected Claim 15 under Section 101 and Section 112, second paragraph. However, these rejections are also now moot because Claim 15 has been cancelled herein. In its place, new method Claim 16 has been added to the case which is more clearly directed to a method for treating benign prostatic hyperplasia in a patient needing such treatment.

In view of the foregoing, it is submitted that the Section 101 and Section 112 rejections have been overcome and should be withdrawn.

III. The Anticipation Rejections.

Turning to the prior art, the Examiner argues that Claims 1 – 12 and 14 are anticipated by the Chen patent. It is respectfully submitted that these rejections are not well taken.

Independent Claims 1 and 2 are both directed to controlled release pharmaceutical formulations which comprise, among other things, a pellet core having a diameter from about 0.5 to about 2.00 millimeters which is coated with a gastroresistant and/or release controlling coating. According to the present disclosure, these very small pellets are each individually formed and coated. Then, a plurality of the individually coated pellet cores may be filled into a capsule or compressed into a tablet as described in the Applicants' specification.

Chen fails to disclose or suggest any type of coated pellet cores having a diameter from about 0.5 to about 2.00 millimeters. Chen refers to a tablet core which may be coated with an enteric coating material. See, for instance, Chen at Col. 2, lines 9 – 21. Chen's tablet cores, however, are not equivalent to the pellet cores called for in the Applicants' claims. Chen's tablet cores are several times larger than the pellet cores specified in the current claims. In Examples 1 – 5, Chen describes the tablet cores as being from 0.2812 inches to 0.3125 inches. Since 1 inch equals 25.4 millimeters, the size of Chen's tablet cores ranges from 7.14 millimeters to 7.94 millimeters, well beyond the Applicants claimed range of from about 0.5 to about 2.00 millimeters.

Given these differences, the Chen reference fails to disclose each and every limitation of Claims 1 – 4, 7 – 12, and 14. Accordingly, for at least this reason, it is respectfully submitted that the anticipation rejections based upon Chen should be withdrawn.

IV. The Obviousness Rejections.

Finally, the Examiner contends that Claims 13 and 15 are obvious over Chen in view of Platteeuw. Claim 15, however, has now been cancelled and replaced with Claim 16.

As for Claims 13 and 16, both of these claims depend from and incorporate all the limitations of Claim 1. The deficiencies of the Chen reference are discussed above. Among other things, Chen fails to disclose a pellet core having a diameter from about 0.5 to about 2.00 millimeters which is coated with a gastroresistant and/or release controlling coating. The Platteeuw reference, on the other hand, is cited only with respect to the use of tamsulosin as an active ingredient. Thus, Platteeuw fails to cure the aforementioned deficiency of the Chen

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reference, and Claims 13 and 16 distinguish over the Examiner's cited combination of Chen taken in view of Platteeuw for at least this reason.

In light of the foregoing, the Applicants respectfully request the Examiner reconsider the application, withdraw the rejections, and issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, the Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,

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